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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,995	03/27/2000	Satoru Nishimura	0213-1431-0	4205

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EXAMINER

EPPS, JANET L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 08/09/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/534,995

Applicant(s)

NISHIMURA ET AL.

Examiner

Janet L. Epps

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6 and 8-18 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 and 8 is/are allowed.
- 6) ☒ Claim(s) 3-6, 9-12 and 14-17 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1, 7 and 19-22 have been cancelled. Claims 2-6, and 8-17 are currently pending in the instant office action.
2. Claim 18 was withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim, for the reasons of record set forth in the prior Office Action. It is noted that the PTO-326 attached to the prior Office Action improperly indicated that claim 18 was rejected, however the prior Office Action indicated that the claim was withdrawn from consideration.
3. The indicated allowability of claims 3 and 9 set forth in the prior Office Action has been withdrawn in view of the following rejection. Furthermore, it is noted that claim 9 was rejected in the prior Office Action, however the attached PTO-326 improperly indicated that it was allowable.
4. Claim 13 remains objected for the reasons of record.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. Applicant's arguments with respect to the rejection of claims 2, 4-6, 8, 10-12, and 14-17, under 35 U.S.C. 102(b) as being anticipated by Nuccio et al., and the rejection of claims 2 and 8 under 35 U.S.C. 102(b) as being anticipated by Rathinasabapathi et al., have been considered but are moot in view of the new ground(s) of rejection of claims 4-6, 10-12, and 14-17, and the allowance of claims 2 and 8 over the prior art and in view of Applicant's amendment.

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7. Applicant's arguments with respect to the rejection of claims 4-6, 9-12, and 14-17 under 35 U.S.C. 112, first paragraph, have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 3-5, 9-12, and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanson et al. (WO 98/30702 A2), or under 35 USC 102(e) as being anticipated by Hanson et al. (US Patent 6,310,271 B1).

The instant claims are drawn to a DNA, which hybridizes to a DNA comprising the nucleotide sequence shown in SEQ ID NO: 1, 3, 5, or 16 under stringent conditions and which encodes a protein having choline monooxygenase activity. According to the specification as filed, page 9, lines 1-6, stringent conditions are those conditions under which highly homologous

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DNAs (i.e. DNAs having 60% homology or more, preferably 80% homology or more) hybridize to each other and DNAs with less homology do not hybridize to each other.

Hanson et al. disclose polynucleotides encoding choline monooxygenase and plants transformed therewith. In particular, Hanson et al. disclose a polynucleotide sequence of 1622 nucleotides in length that comprises 1095 nucleotide matches, and a best local similarity of 83.5% with the nucleotide sequence of SEQ ID NO: 1 of the instant application. Absent evidence to the contrary the polynucleotide sequence encoding a choline monooxygenase gene, disclosed by Hanson et al. would hybridize under stringent conditions to the nucleotide sequence shown in SEQ ID NO: 1 of the instant application. See Figure 2 of both Hanson et al. references.

Additionally, the choline monooxygenase gene of this reference, in particular nucleotides 72-143, comprises a sequence that is 87% identical to the nucleotide sequence according to SEQ ID NO: 16 of the instant invention.

Hanson et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

11. Claims 3-5, 9-12, and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Rathinasabapathi et al. (*Proc. Natl. Acad. Sci, USA, Vol. 94, pp. 3454-3458*)

Rathinasabapathi et al. disclose and characterize a (CMO) isolated from spinach leaves (*Spinacia oleracea*). In particular, Rathinasabapathi et al. disclose a polynucleotide sequence of 1622 nucleotides in length that comprises 1095 nucleotide matches, and a best local similarity of 83.5% with the nucleotide sequence of SEQ ID NO: 1 of the instant application. Absent evidence to the contrary the polynucleotide sequence encoding a choline monooxygenase gene,

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disclosed by Rathinasabapathi et al. would hybridize under stringent conditions to the nucleotide sequence shown in SEQ ID NO: 1 of the instant application. See Figure 4, page 3457.

Additionally, the choline monooxygenase gene of this reference, in particular nucleotides 72-143, comprises a sequence that is 87% identical to the nucleotide sequence according to SEQ ID NO: 16 of the instant invention.

Rathinasabapathi et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

12. Claims 3-6, 9-12, and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Nuccio et al.

Nuccio et al. describe the CMO isolated from spinach, and a recombinant expression cassette comprising said spinach CMO gene for expression in tobacco plants (page 489, Figure 2, (a)). The choline monooxygenase gene utilized in the teachings of Nuccio et al., was that described in Rathinasabapathi et al. (*as described above*). Additionally, this reference describes transgenic tobacco plants expressing spinach CMO (page 489, Figure 2, (b-f)). These transgenic tobacco plants were exposed to salt stress conditions, however the glycine betaine levels in the transgenic plants were very low as observed in unstressed non-transgenic plants. This observation indicates that the CMO+ transgenic tobacco plants were able to resist the effects of an environment of high salinity (see Page 491, and Figure 6). Nuccio et al. also described the subsequent extraction of active choline monooxygenase enzyme after transgenic expression in tobacco (see Experimental Section: RNA, protein and enzyme analyses, page 494).

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Additionally, the choline monooxygenase gene used in this reference (Rathinasabapathi et al.), in particular nucleotides 72-143, comprises a sequence that is 87% identical to the nucleotide sequence according to SEQ ID NO: 16 of the instant invention.

Nuccio et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

Response to Arguments

13. Claims 3-6, 9-12, and 14-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to a DNA, which hybridizes to a DNA comprising the nucleotide sequence shown in SEQ ID NO: 1, 3, 5, or 16 under stringent conditions and which encodes a protein having choline monooxygenase activity. According to the specification as filed, page 9, lines 1-6, stringent conditions are those conditions under which highly homologous DNAs (i.e. DNAs having 60% homology or more, preferably 80% homology or more) hybridize to each other and DNAs with less homology do not hybridize to each other.

The specification as filed provides sufficient guidance with regards to the isolation, characterization, and use of genes encoding proteins according to SEQ ID NO: 2, 4, 6, or 17 wherein said proteins have choline monooxygenase activity or signal peptide activity, wherein said genes have a sequence according to SEQ ID NO: 1, 3, 5, or 16 respectively. However, the specification as filed does not provide a specific structural description of the full scope of nucleotide sequences encompassed by the claimed invention, particularly wherein the nucleic

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acid sequence hybridizes under stringent conditions, *i.e.* DNAs having 60% homology or more to the sequences according to SEQ ID NO: 1, 3, 5, or 16, and still encode a protein that maintains either signal peptide activity or CMO activity. The specification as filed does not provide sufficient guidance and/or instruction that would unambiguously direct one of skill in the art to design the full scope of gene sequences encompassed by the claimed invention.

The claimed sequences encompass all corresponding sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have 60% homology to the claimed sequences, and so forth. The specification provides insufficient written description to support the genus encompassed by the instant claims.

With the exception of the sequences corresponding to SEQ ID NO: 1, 3, 5 and 16, the skilled artisan cannot envision the detailed chemical structure of the encompassed gene sequences according to the present invention, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483. *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

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Therefore, only SEQ ID NO: 1, 3, 5 and 16, but not the full breadth of the claim meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

In view of the above, evidence of possession cannot be properly demonstrated by providing a means to isolate an invention. Therefore, since it appears that further experimentation is required in order to isolate DNA sequences that hybridize under stringent conditions to SEQ ID NO: 1, 3, 5, or 16, which encodes a protein having choline monooxygenase activity or signal peptide activity, Applicants have not provided a sufficient written description that would clearly indicate that Applicants were in possession of the full scope of the claimed invention at the time of filing of the instant Application.

Claim Objections

14. Claims 14-17 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may not serve as a basis for any other multiple dependent claim, either directly or indirectly. See MPEP § 608.01(n).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps, Ph.D. whose telephone number is 703-308-8883.


The examiner can normally be reached on M-T, Thurs-Friday 8:30AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE
August 7, 2002


SEAN MCGARRY
PRIMARY EXAMINER
1635